

Chapter

3

Food

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3-1 CHARACTERISTICS

Subparts

3-101 Condition

Condition

3-101.11 Safe, Unadulterated, and Honestly Presented.*

FOOD shall be safe, unADULTERATED, and, as specified under § 3-601.12, honestly presented.

3-2

**SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS
AND RECORDS**

Subparts

3-201	Sources
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Sources

3-201.11 Compliance with Food Law.*

(A) FOOD shall be obtained from sources that comply with LAW.

(B) FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT.

(C) PACKAGED FOOD shall be labeled as specified in LAW, including 21 CFR 101 FOOD Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under §§ 3-202.17 and 3-202.18.

(D) *Fish, other than MOLLUSCAN SHELLFISH, that are intended for consumption in their raw form and allowed as specified in Subparagraph 3-401.11(C)(1) may be offered for sale or service if they are obtained from a supplier that freezes the FISH as specified under § 3-402.11; or frozen on the PREMISES as specified under § 3-402.11 and records are retained as specified under § 3-402.12.*

(E) WHOLE-MUSCLE, INTACT BEEF steaks that are intended for consumption in an undercooked form without a CONSUMER advisory as specified in ¶ 3-401.11(C) shall be:

(1) Obtained from a FOOD PROCESSING PLANT that packages the steaks and labels them to indicate that they meet the definition of WHOLE-MUSCLE, INTACT BEEF; or

(2) If individually cut in a FOOD ESTABLISHMENT:

(a) Cut from WHOLE-MUSCLE INTACT BEEF that is labeled by a FOOD PROCESSING PLANT to indicate that the beef meets the definition of WHOLE-MUSCLE, INTACT BEEF,

(b) Prepared so they remain intact, and

(c) If PACKAGED for undercooking in a FOOD ESTABLISHMENT, labeled to indicate that they meet the definition of WHOLE-MUSCLE, INTACT BEEF.

(F) MEAT and POULTRY that is not a READY-TO-EAT FOOD and is in a PACKAGED form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in LAW, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

3-201.12 Food in a Hermetically Sealed Container.*

FOOD in a HERMETICALLY SEALED CONTAINER shall be obtained from a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.

3-201.13 Fluid Milk and Milk Products.*

Fluid milk and milk products shall be obtained from sources that comply with GRADE A STANDARDS as specified in LAW.

3-201.14 Fish.*

(A) FISH that are received for sale or service shall be:

- (1) Commercially and legally caught or harvested; or
- (2) APPROVED for sale or service.

(B) MOLLUSCAN SHELLFISH that are recreationally caught may not be received for sale or service.

3-201.15 Molluscan Shellfish.*

(A) MOLLUSCAN SHELLFISH shall be obtained from sources according to LAW and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(B) MOLLUSCAN SHELLFISH received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

3-201.16 Wild Mushrooms.*

(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an APPROVED mushroom identification expert.

(B) *This section does not apply to:*

(1) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the FOOD regulatory agency that has jurisdiction over the operation; or

(2) Wild mushroom species if they are in PACKAGED form and are the product of a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.

3-201.17 Game Animals.*

(A) If GAME ANIMALS are received for sale or service they shall be:

(1) Commercially raised for food and:

(a) Raised slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, or

(b) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, and

(c) Raised, slaughtered, and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem

examination by an APPROVED veterinarian or veterinarian's designee;

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and APPROVED" in accordance with 9 CFR 352 Voluntary Exotic Animal Program or rabbits that are "inspected and certified" in accordance with 9 CFR 354 Rabbit Inspection Program;

(3) As allowed by LAW, for wild GAME ANIMALS that are live-caught:

(a) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, and

(b) Slaughtered and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee; or

(4) As ALLOWED by LAW, for field-dressed wild GAME ANIMALS under a routine inspection program that ensures the animals:

(a) Receive a postmortem examination by an APPROVED veterinarian or veterinarian's designee, or

(b) Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(c) Are processed according to LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.

(B) A GAME ANIMAL may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and Threatened Wildlife and Plants.

**Specifications
for Receiving**

3-202.11 Temperature.*

(A) Except as specified in ¶ (B) of this section, refrigerated, POTENTIALLY HAZARDOUS FOOD shall be at a temperature of 5°C (41°F) or below when received.

(B) If a temperature other than 5°C (41°F) for a POTENTIALLY HAZARDOUS FOOD is specified in LAW governing its distribution, such as LAWS governing milk, MOLLUSCAN SHELLFISH, and shell eggs, the FOOD may be received at the specified temperature.

(C) POTENTIALLY HAZARDOUS FOOD that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 60°C (140°F) or above.

(D) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen.

(E) Upon receipt, POTENTIALLY HAZARDOUS FOOD shall be free of evidence of previous temperature abuse.

3-202.12 Additives.*

FOOD may not contain unAPPROVED FOOD ADDITIVES or ADDITIVES that exceed amounts specified in 21 CFR 170-180 relating to FOOD ADDITIVES, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR 318.7 Approval of substances for use in the preparation of products, or pesticide residues that exceed provisions specified in 40 CFR 185 Tolerances for Pesticides in Food.

3-202.13 Shell Eggs.*

Shell eggs shall be received clean and sound and may not exceed the restricted egg tolerances for U.S. CONSUMER Grade B as specified in 7 CFR Part 56 - Regulations Governing the Grading of Shell Eggs and U.S. Standards, Grades, and Weight classes for Shell Eggs, and 7 CFR Part 59 - Regulations Governing the Inspection of Eggs and Egg Products.

3-202.14 Eggs and Milk Products, Pasteurized.*

(A) Liquid, frozen, and dry eggs and egg products shall be obtained pasteurized.

(B) Fluid and dry milk and milk products complying with GRADE A STANDARDS as specified in LAW shall be obtained pasteurized.

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135 - Frozen Desserts.

(D) Cheese shall be obtained pasteurized *unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 - Cheeses and Related Cheese Products, for curing certain cheese varieties.*

3-202.15 Package Integrity.*

FOOD packages shall be in good condition and protect the integrity of the contents so that the FOOD is not exposed to ADULTERATION or potential contaminants.

3-202.16 Ice.*

Ice for use as a FOOD or a cooling medium shall be made from DRINKING WATER.

3-202.17 Shucked Shellfish, Packaging and Identification.

(A) Raw SHUCKED SHELLFISH shall be obtained in nonreturnable packages which bear a legible label that identifies the:

(1) Name, address, and CERTIFICATION NUMBER of the shucker-packer or repacker of the MOLLUSCAN SHELLFISH; and

(2) The "sell by" date for packages with a capacity of less than 1.87 L (one-half gallon) or the date shucked for packages with a capacity of 1.87 L (one-half gallon) or more.

(B) A package of raw SHUCKED SHELLFISH that does not bear a label

or which bears a label which does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

3-202.18 Shellstock Identification.*

(A) SHELLSTOCK shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships, or reships the SHELLSTOCK, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list:

(1) Except as specified under ¶ (C) of this section, on the harvester's tag or label, the following information in the following order:

(a) The harvester's identification number that is assigned by the SHELLFISH CONTROL AUTHORITY,

(b) The date of harvesting,

(c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the SHELLFISH CONTROL AUTHORITY and including the abbreviation of the name of the state or country in which the shellfish are harvested,

(d) The type and quantity of shellfish, and

(e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days;" and

(2) Except as specified in ¶ (D) of this section, on each dealer's tag or label, the following information in the following order:

(a) The dealer's name and address, and the CERTIFICATION NUMBER assigned by the SHELLFISH CONTROL AUTHORITY,

(b) The original shipper's CERTIFICATION NUMBER including the abbreviation of the name of the state or country in which the shellfish are harvested,

(c) The same information as specified for a harvester's tag under Subparagraphs (A)(1)(b)-(d) of this section, and

(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days."

(B) A container of SHELLSTOCK that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

(C) If a place is provided on the harvester's tag or label for a dealer's name, address, and CERTIFICATION NUMBER, the dealer's information shall be listed first.

(D) If the harvester's tag or label is designed to accommodate each dealer's identification as specified under Subparagraphs (A)(2)(a) and (b) of this section, individual dealer tags or labels need not be provided.

3-202.19 Shellstock, Condition.

When received by a FOOD ESTABLISHMENT, SHELLSTOCK shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or SHELLSTOCK with badly broken shells shall be discarded.

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

(A) Except as specified in ¶¶ (B) and (C) of this section, MOLLUSCAN SHELLFISH may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(B) SHELLSTOCK may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a CONSUMER may be removed from the display or display container and provided to the CONSUMER if:

(1) The source of the SHELLSTOCK on display is identified as specified under § 3-202.18 and recorded as specified under § 3-203.12; and

(2) *The SHELLSTOCK are protected from contamination.*

(C) *SHUCKED SHELLFISH may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a CONSUMER'S request if:*

(1) *The labeling information for the shellfish on display as specified under § 3-202.17 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and*

(2) *The shellfish are protected from contamination.*

3-203.12 Shellstock, Maintaining Identification.*

(A) Except as specified under Subparagraph (B)(2) of this section, SHELLSTOCK tags shall remain attached to the container in which the shellstock are received until the container is empty.

(B) The identity of the source of SHELLSTOCK that are sold or served shall be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date the container is emptied by:

(1) Using an APPROVED record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the SHELLSTOCK are sold or served; and

(2) If SHELLSTOCK are removed from their tagged or labeled container:

(a) Using only 1 tagged or labeled container at a time, or

(b) Using more than 1 tagged or labeled container at a time and obtaining a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 based on a HACCP PLAN that:

(i) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11,

(ii) Preserves source identification by using a record keeping system as specified under Subparagraph (B)(1) of this section, and

(iii) Ensures that SHELLSTOCK from one tagged

or labeled container are not commingled with SHELLSTOCK from another container before being ordered by the CONSUMER.

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Clarification of ¶ 3-301.11(B) of the Food Code **with respect to the phrase "*Except...when otherwise APPROVED*" ...**

The following information is not part of Chapter 3 and is not intended to be included in the codified portion of the Food Code. In cases where the Food Code is adopted through incorporation by reference, this page may be removed.

In response to a 1996 Conference for Food Protection (CFP) Recommendation that ¶ 3-301.11(B) be modified to include the phrase "or when otherwise APPROVED," the 1997 Code was amended accordingly. A 1998 CFP Recommendation further suggested clarification of that added language.

This insert page is provided to alert the reader that FDA has issued, with this Code, clarification of that phrase and its application. Included in Annex 3 is a full discussion of both the Public Health Reasons associated with § 3-301.11 and Administrative Guidelines regarding the criteria under which bare hand contact with ready-to-eat food may be deemed acceptable in meeting the intent of § 3-301.11.

A HACCP-based approach is applied in the clarification in order to establish a system to control the principal hazard (i.e., fecal-oral transmission of foodborne pathogens) that is the target of the Code provision.

A second 1998 CFP Recommendation was made to consult the National Advisory Committee for the Microbiological Criteria for Foods (NACMCF) for its scientific recommendations surrounding the transmission of pathogens from food workers to consumers via ready-to-eat foods. FDA is preparing information with the intent that the NACMCF will review the matter and make recommendations that will be presented at the 2000 CFP meeting.

3-3

PROTECTION FROM CONTAMINATION AFTER RECEIVING

Subparts

- 3-301** Preventing Contamination by Employees
- 3-302** Preventing Food and Ingredient Contamination
- 3-303** Preventing Contamination from Ice Used as a Coolant
- 3-304** Preventing Contamination from Equipment, Utensils, and Linens
- 3-305** Preventing Contamination from the Premises
- 3-306** Preventing Contamination by Consumers
- 3-307** Preventing Contamination from Other Sources

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.*

(A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.

(B) *Except when washing fruits and vegetables as specified under § 3-302.15 or when otherwise APPROVED*, FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.

(C) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form.⁵

3-301.12 Preventing Contamination when Tasting.*

A FOOD EMPLOYEE may not use a UTENSIL more than once to taste FOOD that is to be sold or served.

**Preventing Food
and Ingredient
Contamination**

**3-302.11 Packaged and Unpackaged Food - Separation,
Packaging, and Segregation.***

(A) FOOD shall be protected from cross contamination by:

(1) Separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as vegetables, and

(b) Cooked READY-TO-EAT FOOD;

(2) *Except when combined as ingredients*, separating types of raw animal FOODS from each other such as beef, FISH, lamb, pork, and POULTRY during storage, preparation, holding, and display by:

(a) Using separate EQUIPMENT for each type, or

(b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented, and

(c) Preparing each type of FOOD at different times or in separate areas;

(3) Cleaning EQUIPMENT and UTENSILS as specified under ¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(4) Except as specified in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;

(5) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;

(6) Protecting FOOD containers that are received PACKAGED together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; and

(8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.

(B) *Subparagraph (A)(4) of this section does not apply to:*

(1) *Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;*

(2) *PRIMAL CUTS, quarters, or sides of raw MEAT or slab bacon that are hung on clean, SANITIZED hooks or placed on clean, SANITIZED racks;*

(3) *Whole, uncut, processed MEATS such as country hams, and smoked or cured sausages that are placed on clean, SANITIZED racks;*

(4) *FOOD being cooled as specified under Subparagraph 3-501.15(B)(2); or*

(5) *SHELLSTOCK.*

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Working containers holding FOOD or FOOD ingredients that are removed from their original packages for use in the FOOD ESTABLISHMENT, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the FOOD *except that containers holding FOOD that can be readily and unmistakably recognized such as dry pasta need not be identified.*

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.*

Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and egg-fortified BEVERAGES that are not:

(A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); or

(B) Included in Subparagraph 3-401.11(D).

3-302.14 Protection from Unapproved Additives.*

(A) FOOD shall be protected from contamination that may result from the addition of, as specified in § 3-202.12:

(1) Unsafe or unAPPROVED FOOD or COLOR ADDITIVES; and

(2) Unsafe or unAPPROVED levels of APPROVED FOOD and COLOR ADDITIVES.

(B) A FOOD EMPLOYEE may not:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a FOOD considered to be a good source of vitamin B₁; or

(2) Serve or sell FOOD specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the FOOD ESTABLISHMENT, *except that grapes need not meet this subparagraph.*

3-302.15 Washing Fruits and Vegetables.

(A) Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TO-EAT form except as specified in ¶ (B) of this section and *except that whole, raw fruits and vegetables that are intended for washing by the CONSUMER before consumption need not be washed before they are sold.*

(B) *Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12.*

***Preventing
Contamination
from Ice Used
as a Coolant***

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

After use as a medium for cooling the exterior surfaces of FOOD such as melons or FISH, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT, ice may not be used as FOOD.

3-303.12 Storage or Display of Food in Contact with Water or Ice.

(A) PACKAGED FOOD may not be stored in direct contact with ice or water if the FOOD is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

(B) Except as specified in ¶¶ (C) and (D) of this section, unPACKAGED FOOD may not be stored in direct contact with undrained ice.

(C) *Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.*

(D) *Raw chicken and raw FISH that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.*

Preventing Contamination from Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.*

FOOD shall only contact surfaces of EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code.

3-304.12 In-Use Utensils, Between-Use Storage.

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:

(A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;

(B) In FOOD that is not POTENTIALLY HAZARDOUS with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;

(C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;

(D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;

(E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not POTENTIALLY HAZARDOUS; or

(F) In a container of water if the water is maintained at a temperature of at least 60°C (140°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

3-304.13 Linens and Napkins, Use Limitation.

LINENS and napkins may not be used in contact with FOOD *unless they are used to line a container for the service of FOODS and the LINENS and napkins are replaced each time the container is refilled for a new CONSUMER.*

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths that are in use for wiping FOOD spills shall be used for no other purpose.

(B) Cloths used for wiping FOOD spills shall be:

(1) Dry and used for wiping FOOD spills from TABLEWARE and carry-out containers; or

(2) Wet and cleaned as specified under ¶ 4-802.11(D), stored in a chemical sanitizer at a concentration specified in § 4-501.114, and used for wiping spills from FOOD-CONTACT and nonFOOD-CONTACT SURFACES of EQUIPMENT.

(C) Dry or wet cloths that are used with raw animal FOODS shall be kept separate from cloths used for other purposes, and wet cloths used with raw animal FOODS shall be kept in a separate sanitizing solution.

(D) Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of FOOD debris and visible soil.

3-304.15 Gloves, Use Limitation.

(A) If used, SINGLE-USE gloves shall be used for only one task such as working with READY-TO-EAT FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

(B) Except as specified in ¶ (C) of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with FOOD that is subsequently cooked as specified under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.

(C) Slash-resistant gloves may be used with READY-TO-EAT FOOD that will not be subsequently cooked if the slash-resistant gloves have a SMOOTH, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a SMOOTH, durable, nonabsorbent glove, or a SINGLE-USE glove.

(D) Cloth gloves may not be used in direct contact with FOOD *unless the FOOD is subsequently cooked as required under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.*

3-304.16 Using Clean Tableware for Second Portions and Refills.

(A) Except for refilling a CONSUMER'S drinking cup or container without contact between the pouring UTENSIL and the lip-contact area of the drinking cup or container, FOOD EMPLOYEES may not use TABLEWARE, including SINGLE-SERVICE ARTICLES, soiled by the CONSUMER, to provide second portions or refills.

(B) Except as specified in ¶ (C) of this section, self-service CONSUMERS may not be allowed to use soiled TABLEWARE, including SINGLE-SERVICE ARTICLES, to obtain additional FOOD from the display and serving EQUIPMENT.

(C) Drinking cups and containers may be reused by self-service CONSUMERS if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D).

3-304.17 Refilling Returnables.

(A) A take-home FOOD container returned to a FOOD ESTABLISHMENT may not be refilled at a FOOD ESTABLISHMENT with a POTENTIALLY HAZARDOUS FOOD.

(B) Except as specified in ¶ (C), a take-home FOOD container refilled with FOOD that is not POTENTIALLY HAZARDOUS shall be cleaned as specified under ¶ 4-603.17(B).

(C) Personal take-out BEVERAGE containers, such as thermally insulated bottles, nonspill coffee cups, and promotional BEVERAGE glasses, may be refilled by EMPLOYEES or the CONSUMER if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D).

Preventing Contamination from the Premises

3-305.11 Food Storage.

(A) Except as specified in ¶¶ (B) and (C) of this section, FOOD shall be protected from contamination by storing the FOOD:

(1) In a clean, dry location;

(2) Where it is not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) FOOD in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling EQUIPMENT as specified under § 4-204.122.

(C) Pressurized BEVERAGE containers, cased FOOD in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

(A) In locker rooms;

(B) In toilet rooms;

- (C) In dressing rooms;
- (D) In garbage rooms;
- (E) In mechanical rooms;
- (F) Under sewer lines that are not shielded to intercept potential drips;
- (G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
- (H) Under open stairwells; or
- (I) Under other sources of contamination.

3-305.13 Vended Potentially Hazardous Food, Original Container.

POTENTIALLY HAZARDOUS FOOD dispensed through a VENDING MACHINE shall be in the package in which it was placed at the FOOD ESTABLISHMENT OR FOOD PROCESSING PLANT at which it was prepared.

3-305.14 Food Preparation.

During preparation, unPACKAGED FOOD shall be protected from environmental sources of contamination.

Preventing Contamination by Consumers

3-306.11 Food Display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER before consumption, FOOD on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar FOOD guards; display cases; or other effective means.

3-306.12 Condiments, Protection.

(A) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected FOOD displays provided with the proper UTENSILS, original

containers designed for dispensing, or individual packages or portions.

(B) Condiments at a VENDING MACHINE LOCATION shall be in individual packages or provided in dispensers that are filled at an APPROVED location, such as the FOOD ESTABLISHMENT that provides FOOD to the VENDING MACHINE LOCATION, a FOOD PROCESSING PLANT that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the VENDING MACHINE LOCATION.

3-306.13 Consumer Self-Service Operations.*

(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service. *This paragraph does not apply to CONSUMER self-service of READY-TO-EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish; ready-to-cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked MEATS or CONSUMER-selected ingredients for Mongolian barbecue; or raw, frozen, shell-on shrimp or lobster.*

(B) CONSUMER self-service operations for READY-TO-EAT FOODS shall be provided with suitable UTENSILS or effective dispensing methods that protect the FOOD from contamination.^N

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures.^N

3-306.14 Returned Food and Reservice of Food.*

(A) Except as specified in ¶ (B) of this section, after being served or sold and in the possession of a CONSUMER, FOOD that is unused or returned by the CONSUMER may not be offered as FOOD for human consumption.

(B) Except as specified under ¶ 3-801.11(C), *a container of FOOD that is not POTENTIALLY HAZARDOUS may be transferred from one CONSUMER to another if:*

(1) The FOOD is dispensed so that it is protected from contamination and the container is closed between uses,

such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

(2) The FOOD, such as crackers, salt, or pepper, is in an unopened original PACKAGE and is maintained in sound condition.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

FOOD shall be protected from contamination that may result from a factor or source not specified under Subparts 3-301 - 3-306.

3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

- 3-401 Cooking**
- 3-402 Freezing**
- 3-403 Reheating**

Cooking

3-401.11 Raw Animal Foods.*

(A) Except as specified under ¶ (B) and in ¶¶ (C) and (D) of this section, raw animal FOODS such as eggs, FISH, MEAT, POULTRY, and FOODS containing these raw animal FOODS, shall be cooked to heat all parts of the FOOD to a temperature and for a time that complies with one of the following methods based on the FOOD that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for:

(a) Raw shell eggs that are broken and prepared in response to a CONSUMER'S order and for immediate service, and

(b) Except as specified under Subparagraphs (A)(2) and (3) and ¶ (B) of this section, FISH, MEAT, and pork including GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2);

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and INJECTED MEATS; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw eggs that are not prepared as specified under Subparagraph (A)(1)(a) of this section:

Minimum	
Temperature °C (°F)	Time
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

;or

(3) 74°C (165°F) or above for 15 seconds for POULTRY, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed ratites, or stuffing containing FISH, MEAT, POULTRY, or ratites.

(B) Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham, shall be cooked:

(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 4.5 kg (10 lbs)	4.5 kg (10 lbs) or More
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity ¹	121°C (250°F) or less	121°C (250°F) or less

¹ Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

;and

(2) As specified in the following chart, to heat all parts of the FOOD to a temperature and for the holding time that corresponds to that temperature:

Temperature °C (°F)	Time ¹ in Minutes	Temperature °C (°F)	Time ¹ in Minutes	Temperature °C (°F)	Time ¹ in Minutes
54 (130)	121	58 (136)	32	61 (142)	8
56 (132)	77	59 (138)	19	62 (144)	5
57 (134)	47	60 (140)	12	63 (145)	3

¹ Holding time may include postoven heat rise.

(C) A raw or undercooked WHOLE-MUSCLE, INTACT BEEF steak may be served or offered for sale in a READY-TO-EAT form if:

(1) The FOOD ESTABLISHMENT serves a population that is not a HIGHLY SUSCEPTIBLE POPULATION,

(2) The steak is labeled to indicate that it meets the definition of “WHOLE-MUSCLE, INTACT BEEF” as specified under ¶ 3-201.11(E), and

(3) The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.

(D) A raw animal FOOD such as raw egg, raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, or steak tartare; or a partially cooked FOOD such as lightly cooked FISH, soft cooked eggs, or rare MEAT other than WHOLE-MUSCLE, INTACT BEEF steaks as specified in ¶ (C) of this section, may be served or offered for sale in a READY-TO-EAT form if:

(1) The FOOD ESTABLISHMENT serves a population that is not a HIGHLY SUSCEPTIBLE POPULATION, and

(2) The CONSUMER is informed as specified under § 3-603.11 that to ensure its safety, the FOOD should be cooked as specified under ¶ (A) or (B) of this section; or

(3) The REGULATORY AUTHORITY grants a VARIANCE from ¶ (A) or (B) of this section as specified in § 8-103.10 based on a HACCP PLAN that:

(a) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11,

(b) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe FOOD, and

(c) Verifies that EQUIPMENT and procedures for FOOD preparation and training of FOOD EMPLOYEES at the FOOD ESTABLISHMENT meet the conditions of the VARIANCE.

3-401.12 Microwave Cooking.*

Raw animal FOODS cooked in a microwave oven shall be:

(A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(B) Covered to retain surface moisture;

(C) Heated to a temperature of at least 74°C (165°F) in all parts of the food; and

(D) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 60°C (140°F).

Freezing

3-402.11 Parasite Destruction.*

(A) Except as specified in ¶ (B) of this section, before service or sale in READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH other than MOLLUSCAN SHELLFISH shall be frozen throughout to a temperature of:

- (1) -20°C (-4°F) or below for 168 hours (7 days) in a freezer; or
- (2) -35°C (-31°F) or below for 15 hours in a blast freezer.

*(B) If the FISH are tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern), the FISH may be served or sold in a raw, raw-marinated, or partially cooked READY-TO-EAT form without freezing as specified under ¶ (A) of this section.*

3-402.12 Records, Creation and Retention.

(A) Except as specified in ¶ 3-402.11(B) and ¶ (B) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, the PERSON IN CHARGE shall record the freezing temperature and time to which the FISH are subjected and shall retain the records at the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH.

(B) If the FISH are frozen by a supplier, a written agreement or statement from the supplier stipulating that the FISH supplied are frozen to a temperature and for a time specified under § 3-402.11 may substitute for the records specified under ¶ (A) of this section.

Reheating

3-403.10 Preparation for Immediate Service.

Cooked and refrigerated FOOD that is prepared for immediate service in response to an individual CONSUMER order, such as a roast beef sandwich au jus, may be served at any temperature.

3-403.11 Reheating for Hot Holding.*

(A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, POTENTIALLY HAZARDOUS FOOD that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.

(B) Except as specified under ¶ (C) of this section, POTENTIALLY HAZARDOUS FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.

(C) READY-TO-EAT FOOD taken from a commercially processed, HERMETICALLY SEALED CONTAINER, or from an intact package from a FOOD PROCESSING PLANT that is inspected by the FOOD REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 60°C (140°F) for hot holding.

(D) Reheating for hot holding shall be done rapidly and the time the FOOD is between the temperature specified under ¶ 3-501.16(B) or (C) and 74°C (165°F) may not exceed 2 hours.

(E) *Remaining unsliced portions of roasts of beef that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

- 3-501 Temperature and Time Control**
- 3-502 Specialized Processing Methods**

Temperature and Time Control

3-501.11 Frozen Food.

Stored frozen FOODS shall be maintained frozen.

3-501.12 Potentially Hazardous Food, Slacking.

Frozen POTENTIALLY HAZARDOUS FOOD that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under ¶ 3-501.16(C); or

(B) At any temperature if the FOOD remains frozen.

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, POTENTIALLY HAZARDOUS FOOD shall be thawed:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under ¶ 3-501.16(C); or

(B) Completely submerged under running water:

(1) At a water temperature of 21°C (70°F) or below,

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(C), or

(4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(C), for more than 4 hours including:

(a) The time the FOOD is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the FOOD temperature to 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(C);

(C) As part of a cooking process if the FOOD that is frozen is:

(1) Cooked as specified under ¶ 3-401.11(A) or (B) or § 3-401.12, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process; or

(D) *Using any procedure if a portion of frozen READY-TO-EAT FOOD is thawed and prepared for immediate service in response to an individual CONSUMER'S order.*

3-501.14 Cooling.*

(A) Cooked POTENTIALLY HAZARDOUS FOOD shall be cooled:

(1) Within 2 hours, from 60°C (140°F) to 21°C (70°F); and

(2) Within 4 hours, from 21°C (70°F) to 5°C (41°F) or less, or to 7°C (45°F) as specified under ¶ 3-501.16(C).

(B) POTENTIALLY HAZARDOUS FOOD shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified under ¶ 3-501.16(C) if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.

(C) Except as specified in ¶ (D) of this section, a POTENTIALLY HAZARDOUS FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(D) *Shell eggs need not comply with ¶ (C) of this section if the eggs are placed immediately upon their receipt in refrigerated EQUIPMENT that is capable of maintaining FOOD at 5°C (41°F) or less, or 7°C (45°F) or less as specified under ¶ 3-501.16(C).*

3-501.15 Cooling Methods.

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 by using one or more of the following methods based on the type of FOOD being cooled:

- (1) Placing the FOOD in shallow pans;
- (2) Separating the FOOD into smaller or thinner portions;
- (3) Using rapid cooling EQUIPMENT;
- (4) Stirring the FOOD in a container placed in an ice water bath;
- (5) Using containers that facilitate heat transfer;
- (6) Adding ice as an ingredient; or
- (7) Other effective methods.

(B) When placed in cooling or cold holding EQUIPMENT, FOOD containers in which FOOD is being cooled shall be:

- (1) Arranged in the EQUIPMENT to provide maximum heat transfer through the container walls; and
- (2) Loosely covered, or uncovered if protected from overhead contamination as specified under Subparagraph 3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the FOOD.

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under § 3-501.19, POTENTIALLY HAZARDOUS FOOD shall be maintained:

(A) At 60°C (140°F) or above, *except that roasts cooked to a temperature and for a time specified under ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F); or*

(B) At 5°C (41°F) or less, except as specified under ¶ (C) of this section and §§ 3-501.17, 3-501.18, and 4-204.111.

(C) At 7°C (45°F) or between 7°C (45°F) and 5°C (41°F) in existing refrigeration EQUIPMENT that is not capable of maintaining the FOOD at 5°C (41°F) or less if:

- (1) The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT; and

(2) Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

3-501.17 Ready-to-Eat, Potentially Hazardous Food, Date Marking.*

on-premises preparation

• *prepare and hold cold*

(A) Except as specified in ¶ (E) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and held refrigerated for more than 24 hours in a FOOD ESTABLISHMENT shall be clearly marked at the time of preparation to indicate the date by which the FOOD shall be consumed which is, including the day of preparation:

(1) 7 calendar days or less from the day that the FOOD is prepared, if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days or less from the day the FOOD is prepared, if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(B) Except as specified in ¶ (E) of this section, a READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared in a FOOD ESTABLISHMENT and subsequently frozen, shall be clearly marked:

• *prepare, freeze, thaw, immediate use*

(1) When the FOOD is thawed, to indicate that the FOOD shall be consumed within 24 hours; or

• *prepare, hold cold, freeze, thaw, hold cold*

(2) When the FOOD is placed into the freezer, to indicate the length of time before freezing that the FOOD is held refrigerated and which is, including the day of preparation:

(a) 7 calendar days or less from the day of preparation, if the FOOD is maintained at 5°C (41°F) or less, or

(b) 4 calendar days or less from the day of preparation, if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C); and

(3) When the FOOD is removed from the freezer, to indicate the date by which the FOOD shall be consumed which is:

(a) 7 calendar days or less after the FOOD is removed from the freezer, minus the time before freezing, that the FOOD is

held refrigerated if the FOOD is maintained at 5°C (41°F) or less before and after freezing, or

(b) 4 calendar days or less after the FOOD is removed from the freezer, minus the time before freezing, that the FOOD is held refrigerated if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C) before and after freezing.

commercially processed food

• *open and hold cold*

(C) Except as specified in ¶¶ (E) and (F) of this section, a container of refrigerated, READY-TO-EAT POTENTIALLY HAZARDOUS FOOD prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT, to indicate the date by which the FOOD shall be consumed which is, including the day the original container is opened:

(1) 7 calendar days or less after the original container is opened, if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days or less from the day the original container is opened, if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(D) Except as specified in ¶¶ (E) and (F) of this section, a container of refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and PACKAGED by a FOOD PROCESSING PLANT and subsequently opened and frozen in a FOOD ESTABLISHMENT shall be clearly marked:

• *open, freeze, thaw, immediate use*

(1) When the FOOD is thawed, to indicate that the FOOD shall be consumed within 24 hours; or

• *open, hold cold, freeze, thaw, hold cold*

(2) To indicate the time between the opening of the original container and freezing that the FOOD is held refrigerated and which is, including the day of opening the original container:

(a) 7 calendar days or less, after opening the original container if the FOOD is maintained at 5°C (41°F) or less, or

(b) 4 calendar days or less after opening the original container if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C); and

(3) When the FOOD is removed from the freezer, to indicate the date by which the FOOD shall be consumed which is:

(a) 7 calendar days, minus the time before freezing, that the FOOD is held refrigerated if the FOOD is maintained at 5°C (41°F) or less before and after freezing, or

(b) 4 calendar days, minus the time before freezing, that the FOOD is held refrigerated if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C) before and after freezing.

(E) Paragraphs (A)-(D) of this section do not apply to individual meal portions served or rePACKAGED for sale from a bulk container upon a CONSUMER'S request.

(F) Paragraphs (C) and (D) of this section do not apply to whole, unsliced portions of a cured and processed product with original casing maintained on the remaining portion, such as bologna, salami, or other sausage in a cellulose casing.

3-501.18 Ready-to-Eat, Potentially Hazardous Food, Disposition.*

(A) A FOOD specified under ¶ 3-501.17(A) shall be discarded if not consumed within:

(1) 7 calendar days from the date of preparation if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days from the date of preparation if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(B) A FOOD specified under Subparagraph 3-501.17(B)(1) or (D)(1) shall be discarded if not consumed within 24 hours after thawing.

(C) A FOOD specified under Subparagraphs 3-501.17(B)(2) and (3) or (D)(2) and (3) shall be discarded on or before the most recent date marked on the FOOD container or PACKAGE if the FOOD is not consumed by that date.

(D) A FOOD specified under ¶ 3-501.17(C) shall be discarded if not consumed within, including the day of opening the original container:

(1) 7 calendar days after the date that the original PACKAGE is opened in a FOOD ESTABLISHMENT if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days after the date that the original PACKAGE is opened in a FOOD ESTABLISHMENT if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(E) A FOOD specified under ¶ 3-501.17(A), (B), (C), or (D) shall be discarded if the FOOD is:

(1) Marked with the date specified under ¶ 3-501.17(A), (B), (C), or (D) and the FOOD is not consumed before the most recent date expires;

(2) In a container or PACKAGE which does not bear a date or time; or

(3) Inappropriately marked with a date or time that exceeds the date or time specified under ¶ 3-501.17(A), (B), (C), or (D).

(F) Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared in a FOOD ESTABLISHMENT and dispensed through a VENDING MACHINE with an automatic shut-off control that is activated at a temperature of:

(1) 5°C (41°F) shall be discarded if not sold within 7 days; or

(2) 7°C (45°F) shall be discarded if not sold within 4 days.

(G) A refrigerated, potentially hazardous, READY-TO-EAT FOOD ingredient or a portion of a refrigerated, potentially hazardous, READY-TO-EAT FOOD that is subsequently combined with additional ingredients or portions of FOOD shall retain the date marking of the earliest or first-prepared ingredient or portion and shall be discarded as specified under ¶¶ 3-501.18(A) - (F).

3-501.19 Time as a Public Health Control.*

(A) Except as specified under ¶ (B) of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD before cooking, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is displayed or held for service for immediate consumption:

(1) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control,

(2) The FOOD shall be cooked and served, served if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control,

(3) The FOOD in unmarked containers or packages or marked to exceed a 4 hour limit shall be discarded, and

(4) Written procedures shall be maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request, that ensure compliance with:

(a) Subparagraphs (A)(1)-(4) of this section, and

(b) § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.

(B) In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, time only, rather than time in conjunction with temperature, may not be used as the public health control for raw eggs.

**Specialized
Processing
Methods**

3-502.11 Variance Requirement.*

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; curing FOOD; brewing alcoholic BEVERAGES; using FOOD ADDITIVES or adding components such as vinegar as a method of FOOD preservation rather than as a method of flavor enhancement or to render a FOOD so that it is not POTENTIALLY HAZARDOUS; packaging FOOD using a REDUCED OXYGEN PACKAGING method *except as specified under § 3-502.12 where a barrier to **Clostridium botulinum** in addition to refrigeration exists*; custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; or preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE.

3-502.12 Reduced Oxygen Packaging, Criteria.*

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and **Clostridium botulinum** is identified as a microbiological HAZARD in the final

**Clostridium
botulinum
Controls**

PACKAGED form shall ensure that there are at least two barriers in place to control the growth and toxin formation of ***C. botulinum***.

(B) A FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:

(1) Identifies the FOOD to be PACKAGED;

(2) Limits the FOOD PACKAGED to a FOOD that does not support the growth of ***Clostridium botulinum*** because it complies with one of the following:

(a) Has an a_w of 0.91 or less,

(b) Has a pH of 4.6 or less,

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the U.S.D.A. using substances specified in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 Restrictions on the use of substances in poultry products and is received in an intact package, or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT or raw POULTRY;

(3) Specifies methods for maintaining FOOD at 5°C (41°F) or below;

(4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(a) Maintain the FOOD at 5°C (41°F) or below, and

(b) Discard the FOOD if within 14 calendar days of its packaging it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;

(5) Limits the shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(6) Includes operational procedures that:

(a) Prohibit contacting FOOD with bare hands,

(b) Identify a designated area and the method by which:

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and

(ii) Access to the processing EQUIPMENT is restricted to responsible trained personnel familiar with the potential HAZARDS of the operation, and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and

(7) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:

(a) Concepts required for a safe operation,

(b) EQUIPMENT and facilities, and

(c) Procedures specified under Subparagraph (B)(6) of this section and ¶ 8-201.14(D).

(C) *Except for FISH that is frozen before, during, and after packaging*, a FOOD ESTABLISHMENT may not package FISH using a REDUCED OXYGEN PACKAGING method.

3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING

Subparts

3-601	Accurate Representation
3-602	Labeling
3-603	Consumer Advisory

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and Standards of Identity or Composition, and the general requirements in 21 CFR 130 - Food Standards: General and 9 CFR 319 Subpart A - General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food Labeling, and 9 CFR 317 Labeling, Marking Devices, and Containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the FOOD;

- (3) An accurate declaration of the quantity of contents;
- (4) The name and place of business of the manufacturer, packer, or distributor; and
- (5) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3)-(5), nutrition labeling as specified in 21 CFR 101 - FOOD Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

- (1) The manufacturer's or processor's label that was provided with the FOOD; or
- (2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

- (1) *A health, nutrient content, or other claim is not made;*
- (2) *There are no state or local LAWS requiring labeling; and*
- (3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

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Current Status of Consumer Advisory Language **Regarding § 3-603.11**

The following information is not part of Chapter 3 and is not intended to be included in the codified portion of the Food Code. It is inserted here to provide a summary of recent events surrounding the matter of a consumer advisory, addressed in § 3-603.11 of the Code. In cases where the Food Code is adopted through incorporation by reference, this page may be removed.

A consensus as to what constitutes satisfactory compliance with § 3-603.11 was reached at the 1998 Conference for Food Protection (CFP) meeting. A third option for the consumer “reminder” was added later. This insert page is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Included in Annex 3 is a full discussion of the evolution of the 1998 CFP consensus, satisfactory compliance, applicability of the Code provision, and the meaning and application of the phrase that appears in § 3-603.11, i.e., “or otherwise processed to eliminate pathogens.”

There are two components to satisfactory compliance: Disclosure and Reminder.

Disclosure is satisfied when:

- (1) Items are described, such as:
 - (a) Oysters on the half-shell (raw oysters),
 - (b) Raw-egg Caesar salad, and
 - (c) Hamburgers (can be cooked to order); or
- (2) Items are asterisked to a footnote that states that the items:
 - (a) Are served raw or undercooked, or
 - (b) Contain (or may contain) raw or undercooked ingredients.

Reminder is satisfied when the items requiring disclosure are asterisked to a footnote that states:

- (1) Regarding the safety of these items, written information is available upon request;¹
- (2) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; or
- (3) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.

¹Essential criteria for such written information are being developed and will be made available, with a downloadable model brochure, on the CFSAN Web Page at <http://www.cfsan.fda.gov>. All brochures must meet these essential criteria.

**Consumer
Advisory**

**3-603.11 Consumption of Animal Foods that are Raw,
Undercooked, or Not Otherwise Processed to
Eliminate Pathogens.***

Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under ¶ 3-801.11(D), if an animal FOOD such as beef, eggs, FISH, lamb, milk, pork, POULTRY, or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a READY-TO-EAT form as a deli, menu, vended, or other item; or as a raw ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS by brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means of the significantly increased risk associated with certain especially vulnerable CONSUMERS eating such FOODS in raw or undercooked form.

3-7 CONTAMINATED FOOD

Subpart

3-701 Disposition

Disposition

**3-701.11 Discarding or Reconditioning Unsafe, Adulterated,
or Contaminated Food.***

(A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be reconditioned according to an APPROVED procedure or discarded.

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 through .17 shall be discarded.

(C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been restricted or excluded as specified under § 2-201.12 shall be discarded.

(D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded.

3-8

SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

Subpart

3-801

Additional Safeguards

Additional Safeguards

3-801.11

Pasteurized Foods, Prohibited Reservice, and Prohibited Food.*

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) PrePACKAGED JUICE or a prePACKAGED beverage containing JUICE, that bears a warning label as specified in 21 CFR, Section 101.17(g) Food Labeling, may not be served or offered for sale;

(B) Pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of:

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, egg nog, ice cream, and egg-fortified BEVERAGES, and

(2) Except as specified in ¶ (E) of this section, recipes in which more than one egg is broken and the eggs are combined;

(C) FOOD in an unopened original package may not be re-served; and

(D) The following FOODS may not be served or offered for sale in a READY-TO-EAT form:

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare,

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked eggs that are made from raw shell eggs, and meringue, and

(3) Raw seed sprouts.

(E) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw eggs are combined immediately before cooking for one CONSUMER'S serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled eggs;*

(2) *The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a READY-TO-EAT form, such as a cake, muffin, or bread; or*

(3) *The preparation of the food is conducted under a HACCP PLAN that:*

(a) *Identifies the FOOD to be prepared,*

(b) *Prohibits contacting READY-TO-EAT FOOD with bare hands,*

(c) *Includes specifications and practices that ensure:*

(i) **Salmonella Enteritidis** *growth is controlled before and after cooking, and*

(ii) **Salmonella Enteritidis** *is destroyed by cooking the eggs according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*

(i) *Control cross contamination of READY-TO-EAT FOOD with raw eggs, and*

(ii) *Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES, and*

(e) *Describes the training program that ensures that the FOOD EMPLOYEE responsible for the preparation of the FOOD understands the*

procedures to be used.